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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,656	11/24/2003	George Frey	4002-3429/PC845.00	4638

52196 7590 02/24/2006

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,656

Applicant(s)

FREY ET AL.

Examiner

Robert W. Amareld, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 49-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 32-48 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-48, drawn to surgical instrumentation system, classified in class 606, subclass 57.
- II. Claims 49-56, drawn to a method of spinal surgery, classified in class 606, subclass 606/90.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a material different process such as engaging any two bones connected by a joint and distracting them, which doesn't require the particulars of spinal surgery.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Douglas Collier on 1/10/06 a provisional election was made without traverse to prosecute the invention of the surgical instrumentation system, claims 1-48. Affirmation of this election must be made by applicant in replying to this Office action. Claim 49-56 are withdrawn from further

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consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

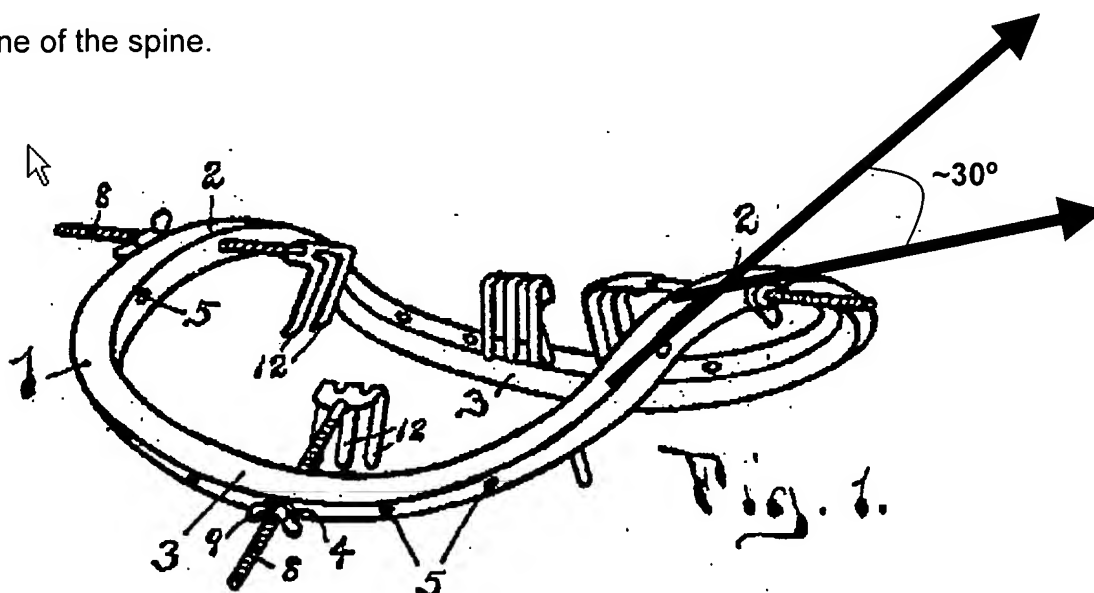
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 15 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by McCrory (US Pat#1400616). McCrory discloses a frame with portions lining in a first and

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second plane, where the planes form an angle (Figure 1) where the angle is $\sim 30^\circ$ as shown in the drawing below. A number of retractors are attached to the frame where there are 4 retractors, each retractor has a parallel opposing counterpart and extend transversely to a plane where the members are fully capable of encircling an opening and form an oval shape on the frame. The device is fully capable of being positioned along the spine where a portion will lie posterior and/or posterior-lateral and along the mid-line of the spine.



Claims 41, 44 & 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kluger (DE 8704901 U). Kluger discloses first and second anchors (19) and a frame (2) lying in at least one plane where first (4) and second (2) distractor mechanisms are attachable to the frame and extend transversely and are engagable to the anchors where portion 3 includes a locking wheel mechanism to fixedly secure the device and the device includes the pivoting portions 5 and 5a, allowing for a pivotal relationship with the anchors where the anchors are multi axial screws as demonstrated by the circular rotation aspect (32) of Figures 5 and 6)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11, 13, 17, 21-27, 32, 33, 36-43 & 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory (US Pat# 1400616) in view of Mayer (US Pat# 5728046). McCrory is discussed supra. However, McCrory does not disclose anchors attachable to the vertebrae. Mayer teaches a pair of distractor mechanisms (32) attachable to anchors (36), which are bone screws where the bone screws are attachable to vertebrae (Col. 6, lines 37-47), where the anchors have anchor extensions (35) and the retractor body (32) is about the anchor extensions where the receptacle in the in the retractor (visible in Figure 3) is configured to capture the anchor extension and the distractors are attachable to a frame. Mayer further discloses distractors with locking engagement to fixedly secure (30, 31) where the anchors are fully capable of pivoting relative to the frame, by rotation along the circular path of the securing threaded area (29), additionally the elastic detent device (24, 25) allows for locking in various positions (col. 3, lines 10-20), and are effective releasable clamping devices where Mayer teaches up to 4 of these clamping devices (14,15, 24, 25). The various adjustment mechanisms of Mayer include a handle ((14,15, 24, 25) or (12, 13, 22, 23)) with shaft assembly with engaging threads at the end of the shaft as seen in Figure 1 where the adjustment may occur along teeth. Mayer's teachings are in the same field of endeavor

or the analogous art of retractors for the purpose of maintaining an opening during surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of securing members with various adjustment and locking mechanism, as taught by Mayer, to the retractor frame as per McCrory, in order to provide the ability of distraction to the device.

Claim 12, 14, 18-20, 28, 34 & 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory (US Pat# 1400616) in view of Mayer (US Pat# 5728046) as disclosed above and further in view of Foley (US Pub# 20020161368). McCrory and Mayer do not disclose multi-axial fixation screw. Foley teaches multi-axial fixation screws (P 0068) for the purposes of fixation to vertebrae (Figure 21) where the fixation screws contain a yoke (p0068-0071) where the yoke is pivotally attached to a threaded shank and the yoke (68) is an inner cylindrical shaft received in the distal end of an outer shaft (P 0071-0072) that is adapted to fixedly engage the yoke where the inner and outer shaft remain movable relative to one another and the screw remains pivotal. The yoke has two arms as shown in Figure 1, where the arms receive the poly-axial screw as well as portion 90. Foley's teachings are in the same field of endeavor or the analogous art of fixation for the purpose of poly-axially fixedly attaching to the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of poly-axial screws with a yoke, as taught by Foley, to the retractor-distraction system as per McCrory and Mayer, in order to attach the distraction portion of the device to the spine.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clifton, US Pub# 20030149341-retractor; ST.Onge, US Pat# 6605088-bone setting device; Janowski, US Pub # 20030153910- external fixation; Bates, US Pat# 1157202- surgical apparatus; Arnold, US Pat# 1839726-circular retractor; Wexler, US Pat# 2473266- retractor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino

Robert W Amareld, Jr.
Examiner
Art Unit 3738

